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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,038	11/17/2006	Edward Zbygniew Nowak	061170-0235	5625

31824 7590 09/30/2008
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EXAMINER

PURDY, KYLE A

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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09/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,038	Applicant(s) NOWAK, EDWARD ZBYGNIEW	
	Examiner Kyle Purdy	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-16,18-26 and 28-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-3,5-15,29 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,18-26,28,30-35 and 37-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Restriction Requirement

1. Applicant's election of Group II in the reply filed on 06/27/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). This requirement is deemed proper and made FINAL.

Status of Application

2. Claims 1-3, 5-16, 18-26 and 28-40 are pending, claims 1-3, 5-15 and 29 are withdrawn as being directed to non-elected species/invention and claims 16, 18-26, 28, 30-35 and 37-39 are presented for examination on the merits. The following rejections are made.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claims 19, 24 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

5. Claim 19 recites, 'the active ingredient continues to move or be transported after the curing stage'. It is unclear as to where the active ingredient is moving to. Is it simply moving around in the film to which it has been cast in or applied to? Clarification is requested.

6. Note, claim 19 will be interpreted to mean that the drug moves in the layer which it was cast.

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7. Claim 24 recites the limitation "transport medium". However, 'transport medium' is not found anywhere in the claims from which claim 24 depends. There is insufficient antecedent basis for this limitation in the claim. Correction is required.

8. Claim 35 recites, 'a multicellular dosage' be made from the film of claim 16. However, it is not clear what Applicant intends to claim by the recitation of a multicellular dosage form. Moreover, no where in the specification does Applicant define what is encompassed by multicellular dosage form. Does Applicant intend to claim a multilayered dosage form? Clarification is required.

9. Note, claim 35 will be interpreted to mean a multilayered form.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

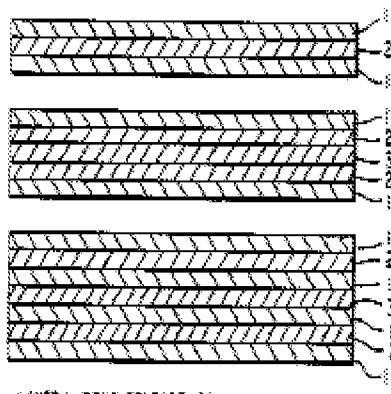
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 16, 18-20, 23, 24, 26, 28, 31, 35 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Inaba et al. (US 4552751).

12. Inaba is directed to long-lasting multi-layered film preparations. The structure of the films are disclosed to have the following structures:

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(see abstract).

Layer 1 corresponds to a drug release controlling layer and Layers 2 and 3 correspond to drug storing layers. The multilayered dosage forms are gelatin free. The polymers used in the films include hydroxypropyl methylcellulose and polyvinylpyrrolidone (see column 2, line 15). The method of making such films is as follows: A) make a drug-free film layer liquid formulation; B) cast A to form the film; C) make a drug-containing film layer liquid formulation; D) pour drug film liquid onto film A and let dry; and E) repeat indefinitely until desired dosage form has been prepared (see column 5, lines 10-20 and Example 1; see instant claims 16, 23, 24, 26, 28, 31, 35 and 40). It is noted that Applicants definition of monolith is simply a multi-layered dosage form. It should be pointed out that as one layer is drug free and one layer contains drug, there is necessarily a concentration gradient present in the film (see instant claim 18). Because the references multi-layered film compositions are identical to the instant claims, the final film would inherently have a homogenous structure.

13. The instant claims are product-by-process claims and are not limited to the manipulations of the recited steps, only the structure implied by those steps. So although Inaba may slightly differ in their process of making such films, the final product anticipates the instantly claim films.

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14. Therefore, Inaba properly anticipates the instantly rejected claims.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 25 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view of Fagen et al. (US 2003/0183643).

17. Inaba is relied upon for disclosure described in the rejection of claims 16 under 35 U.S.C. 102(b).

18. Inaba teaches a multilayered film which possess five layers (see Example 5 and claim 11; see instant claim 32). Moreover, Figure 1 illustrates a film form which has 7 layers.

19. Inaba fails to teach the film being packaged to form a dose unit.

20. Fagen cures this deficiency. Fagen is directed to packaging of films such that individual sheets of the film are dispensed one at a time (see [0001]; see instant claim 25). It is taught that the packaging is useful because it protects unused products during repeated opening and closing (see [0005]).

21. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Inaba and Fagen to arrive a product wherein the films are packaged to form a unit dose. One would have been motivated to package the unit doses of the films disclosed by Inaba because it would protect the unused films thereby

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preventing exposure to moisture and potential environmental degradation of the drug and/or film. Therefore, a packaged unit dose of a drug loaded non-gelatin film is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

22. Claims 21, 22 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view of Patel et al. (US 2004/0253434).

23. Inaba is relied upon for disclosure described in the rejection of claims 16 and 18-20 under 35 U.S.C. 102(b).

24. Inaba fails teach the film as being coiled or zigzag.

25. Patel cures these deficiencies. Patel is directed to water-soluble films systems with actives entrapped therein (see abstract). It is disclosed that the films can be in a rolled (i.e. coiled) or fanfold form (i.e. zigzag shape) (see [0197] and page 3). It is taught that such a shape is useful to selectively entrap interacting/non-interacting materials and their combinations (see abstract).

26. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Inaba and Patel with a reasonable expectation for success in arriving at a film composition wherein the film is in a coiled or zigzag shape. Inaba is discussed above. Briefly, Inaba discloses a non-gelatin film that has an drug solution applied to it and subsequently cured. Inaba fails to teach the shape of the film. Patel cures these deficiencies. Patel teaches that their water-soluble films are capable of being shaped into coiled or zigzag forms. One would have been motivated to shape the films to such forms because it

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would aid in entrapping interacting and non-interacting materials. Moreover, such shapes would provide a more compact and convenient means for retaining the film material. Therefore, a non-gelatin film in the shape of a coil or zigzag is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

27. Claims 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view Brown et al. (US 6783768).

28. Inaba is relied upon for disclosure described in the rejection of claim 16 under 35 U.S.C. 102(b).

29. Inaba fails to teach the film as being employed to coat tablets or capsules.

30. Brown cures these deficiencies. Brown is directed to coating tablet cores with pharmaceutically active films (see abstract). The coating may be applied electrostatically or by inkjet (see column 16, lines 20-25). It is taught that such coatings can help to reduce the size of the dosage form as well as to minimize variation in the dose delivered (see column 1- column 2).

31. Therefore, it would have be obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Inaba and Brown with a reasonable expectation for success in arriving at a film capable of coating a tablet. One would have been motivated to coat a tablet or capsule with the film of Inaba because it would reduce the size of the dosage form by minimizing the amount of inert ingredients as well as help to reduce the variation in the dosage delivered. Therefore, a tablet or capsule coated with a drug containing non-gelatin film is

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prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

32. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Inaba et al. (US 4552751) in view Fagen et al. (US 2003/0183643) and Lynn et al. (US 7112361).

33. Inaba and Fagen is relied upon for disclosure described in the rejection of claim 25 under 35 U.S.C. 102(b).

34. Inaba and Fagen fail to teach the number of layers on the monolith as being greater than 10.

35. Lynn cures this deficiency. Lynn is directed to decomposable films containing polyelectrolytes. It is taught that the films can contain pharmaceutical actives. Lynn teaches a film which has 10 bilayers, wherein each bilayer comprises of poly(b-amino ester) and poly(sodium 4-styrenesulfonate). Thus, the final film has 20 layers (see instant claims 33 and 34). It is taught that the number of layers controls the release rate of the entrapped substances, i.e. a drug (see column 11, line 25).

36. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Inaba, Fagen and Lynn with a reasonable expectation for success in arriving at a multilayered film composition which comprises more than 10 layers. Inaba suggests such a composition by teaching that multi-layered dosage form is to have at least one drug storing layer and at least two drug releasing layers. Furthermore, Inaba teaches a composition which has 7 layers. Based on the teaching of Inaba one would have been

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motivated to make a film composition having multiple layers. If such a result was a film product that had 10 layers, then that would be a product of ordinary skill and common sense because Inaba indirectly suggests making such a composition. Regardless, Inaba fail to explicitly teach a multilayered film having at least 10 layers. Lynn cures this deficiency. Lynn teaches a multilayer film formulation that can have up to 20 layers. One would have been motivated to modify the teaching of Inaba because in doing so would result in adjusting the release rate of the drugs from the dosage form. Therefore, a non-gelatin film possessing more than 10 layers is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in absence of evidence to the contrary.

Conclusion

37. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

38. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau, can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

39. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*/Kyle Purdy/
Examiner, Art Unit 1611
September 16, 2008*

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611